Safinamide Phase III MOTION and SETTLE study results presented at 2013 American Academy of Neurology (AAN) Annual Meeting

Safinamide significantly improves motor function (primary efficacy variable: UPDRS III) in early Parkinson’s disease (PD) patients on a single dopamine agonist at a stable dose (MOTION study)

Safinamide significantly improves motor fluctuations (primary efficacy variable: ON time without troublesome dyskinesia) in mid-to late stage PD patients on levodopa and other PD drugs at a stable dose (SETTLE study)

Safinamide was very well tolerated in both studies with low drop out rates

Safinamide filing for regulatory approval as add-on in early and mid-to late PD patients in EU and US expected in Q4/2013

Milan, Italy, March 19, 2013 – Newron Pharmaceuticals S.p.A. (“Newron”), a research and development company focused on novel CNS and pain therapies, and its partner Zambon S.p.A., a pharmaceutical company strongly committed to the respiratory, primary care and CNS therapeutic areas, presented results from the Phase III studies, MOTION and SETTLE, for safinamide at the 65th Annual Meeting of the American Academy of Neurology (AAN), on March 18, 2013.

MOTION* study was a six-month (24-week), randomized, double-blind, placebo-controlled international Phase III trial. It enrolled patients with early idiopathic PD (less than five years of disease duration) treated with a stable dose of a single dopamine agonist for at least four weeks. 679 patients were randomized equally to receive once daily safinamide 50 mg, or 100 mg, or matching placebo tablets as adjunctive treatment to a single dopamine agonist at a fixed dose. In accordance with international regulatory guidelines, the primary efficacy variable of the trial was the change in motor symptoms assessed by the change in the Unified Parkinson’s Disease Rating Scale (UPDRS) Part III score from baseline to week 24.

Safinamide was very well tolerated. 607 patients completed the trial; the drop-out rate was similar in all three treatment groups (approx. 11%). The most commonly reported adverse events were nausea, dizziness, somnolence, headache and back pain, with no significant difference in the incidence of any of these events among treatment groups. Similarly, the incidence of treatment induced abnormalities in laboratory results, ophthalmological examinations, vital signs and ECG was similar in all groups.
Analyses (On treatment, ANCOVA-LOCF) performed in the ITT population and the modified dopamine agonist monotherapy population (excluding 13 patients not meeting the major inclusion criteria of stable, dopamine agonist monotherapy) provided similar results. Treatment with safinamide 100 mg/day, compared with dopamine agonist alone (=placebo), improved the UPDRS III total score (change from base line to endpoint) by 1.04 ± 0.58 (p=0.07) and 1.20 ± 0.58 (p=0.039) in the ITT and modified dopamine agonist monotherapy population, respectively. Significant benefits of safinamide 100 mg/day were also noted in the PDQ39 (Parkinson’s Disease Quality of Life) and EQ-5D (European Quality of Life 5 domains).

SETTLE** study was a six-month (24-week), randomized, double-blind, placebo-controlled international Phase III trial. It enrolled 549 patients with mid-to late-stage idiopathic PD (more than three years of disease duration) treated with optimized, stable doses of levodopa and standard of care (dopamine agonist, COMT inhibitor, anticholinergic and/or amantadine) for at least four weeks. Patients who were experiencing a minimum of one and a half hours of “OFF” time during the day were randomized equally to treatment with once a day safinamide (50-100mg) or placebo (standard of care including levodopa), as adjunctive treatment. Based on discussions with the regulatory authorities, the primary endpoint of the trial was the change in daily “ON” time, as assessed by the patient completed daily diary cards (18 hours/day).

Safinamide was very well tolerated. 484 patients completed the trial; the drop-out rate was similar in both treatment groups (approx. 12%). The most commonly reported adverse events were nausea, urinary tract infections, falls, back pain and dyskinesia. Transient dyskinesia occurred more frequently with safinamide, but was mainly mild, and was not associated with treatment discontinuation. Similarly, the incidence of treatment induced abnormalities in laboratory results, ophthalmological examinations, vital signs and ECG was similar in all groups.

Analyses (On treatment, ANCOVA-LOCF) performed in the ITT population showed treatment with safinamide 50-100 mg/day significantly improved ON-Time without troublesome dyskinesia compared to placebo by 0.96 ± 0.21 hours (p<0.01) in the ITT. Significant benefits of safinamide 50-100 mg/day were also reported in OFF-time, Motor symptoms (UPDRS III), PDQ39, EQ-5D, clinical global impression of change and severity, and OFF-time post morning dose of levodopa.

“These results are extremely encouraging as they replicate previously reported results from safinamide studies in early and mid-to late stage PD patients. Based on the favourable side effect profile of safinamide, these benefits indicate safinamide will be a novel addition to the currently available therapeutic options for PD patients, as it will be the first add-on treatment for patients in both early and mid-to late PD” said Ravi Anand, Newron’s CMO.

“The results of SETTLE and MOTION show clear and multiple evidence of efficacy combined with a unique safety and tolerability profile. We are pleased to offer new hope to patients with PD” said Marco Sardina, Zambon’s CSO.
MOTION* and SETTLE** results are part of the clinical development program of safinamide, together with completed studies 009, 015, 016, designed to support an application for marketing authorization of safinamide as both an add-on therapy to dopamine agonist therapy in patients with early PD and as an add-on to levodopa therapy in patients with advanced PD. Newron and its partner Zambon plan to submit in the US and EU in Q4/2013.

Further MOTION and SETTLE study results after completion of ongoing analyses will be presented at the upcoming MDS meeting in June 2013.

* MOTION: SafinaMide add-On To dopamine agonist for early Idiopathic Parkinson’s disease with motor fluctuations
** SETTLE: SafinamidE Treatment as add-on To LEvodopa in idiopathic Parkinson’s disease with motor fluctuations

Newron will host a webcast for investors, analysts and the press today starting at 08:30 am CET. To access this event please follow the below instructions:

Conference call dial-in numbers
UK:    +44 203 059 58 62
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The abstracts presented at the AAN, the Annual Report, including the IFRS Consolidated Financial Statements, and the Italian statutory financial statements are available for download at: http://www.newron.com/ENG/Default.aspx?SEZ=5&PAG=122

About safinamide
Safinamide, an alpha-aminoamide, is currently being developed by Newron as an add-on therapy to dopamine agonists or to levodopa in patients with early or mid- to late-stage Parkinson’s disease (PD). It is believed to have both dopaminergic and non dopaminergic activities, including selective and reversible inhibition of monoamine oxidase B (MAO-B), activity-dependent sodium channel antagonism and inhibition of glutamate release in vitro.
About Newron Pharmaceuticals
Newron (SIX: NWRN) is a biopharmaceutical company focused on novel therapies for diseases of the Central Nervous System (CNS) and pain. The Company is headquartered in Bresso near Milan, Italy. Based on the phase III results of safinamide for treatment of Parkinson’s disease, Newron is working to expedite the global filing of the compound, together with its partners. Zambon Group has the rights to commercialise safinamide globally, excluding Japan and other key Asian territories, and Meiji Seika has the rights to develop and commercialise safinamide in Japan and other key Asian territories. Newron’s additional projects are primarily addressed towards highly promising treatments for rare diseases and are at various stages of preclinical and clinical development, including sNN0031 for Parkinson’s disease, sarizotan for Rett’s syndrome, sNN0029 for ALS, ralfinamide for specific pain indications, and NW-3509 as potential first add-on therapy for the treatment of schizophrenia. www.newron.com

About Zambon
Zambon is a leading Italian pharmaceutical and fine-chemical multinational company, that has earned a strong reputation over the years for high quality products and services. Zambon is well-established in 3 therapeutic areas: respiratory, pain and woman care, and is very strongly committed to its entry into the CNS space. Zambon SpA produces high quality products thanks to the management of the whole production chain which involves Zach (Zambon chemical), a privileged partner for API, custom synthesis and generic products. The Group is strongly working on the treatment of the chronic respiratory diseases as BPCO and on the CNS therapeutic area with safinamide for the Parkinson treatment. Zambon is headquartered in Milan and was established in 1906 in Vicenza. Zambon is present in 15 countries with more than 2,600 employees with manufacturing units in Switzerland, France, China and Brazil. For details on Zambon please see: www.zambongroup.com

For more information, contact:

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“target”, and other words and terms of similar meaning. All statements, other than historical facts, contained herein regarding Newron’s strategy, goals, plans, future financial position, projected revenues and costs and prospects are forward-looking statements. By their very nature, such statements and assumptions involve inherent risks and uncertainties, both general and specific, and risks exist that predictions, forecasts, projections and other outcomes described, assumed or implied therein will not be achieved. Future events and actual results could differ materially from those set out in, contemplated by or underlying the forward-looking statements due to a number of important factors. These factors include (without limitation) (1) uncertainties in the discovery, development or marketing of products, including without limitation negative results of clinical trials or research projects or unexpected side effects, (2) delay or inability in obtaining regulatory approvals or bringing products to market, (3) future market acceptance of products, (4) loss of or inability to obtain adequate protection for intellectual property rights, (5) inability to raise additional funds, (6) success of existing and entry into future collaborations and licensing agreements, (7) litigation, (8) loss of key executive or other employees, (9) adverse publicity and news coverage, and (10) competition, regulatory, legislative and judicial developments or changes in market and/or overall economic conditions. Newron may not actually achieve the plans, intentions or expectations disclosed in forward-looking statements and assumptions underlying any such statements may prove wrong. Investors should therefore not place undue reliance on them. There can be no assurance that actual results of Newron’s research programmes, development activities, commercialisation plans, collaborations and operations will not differ materially from the expectations set out in such forward-looking statements or underlying assumptions. Newron does not undertake any obligation to publicly up-date or revise forward looking statements except as may be required by applicable regulations of the SIX Swiss Exchange where the shares of Newron are listed. This document does not contain or constitute an offer or invitation to purchase or subscribe for any securities of Newron and no part of it shall form the basis of or be relied upon in connection with any contract or commitment whatsoever.